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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,530

09/01/2006

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

NOTIFICATION DATE

DELIVERY MODE

04/28/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,530	<b>Applicant(s)</b> HUSCHMAND NIA ET AL.	
	<b>Examiner</b> Brian Szmaj	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/1/06; 1/18/07</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

***Claim Objections***

1. Claim 18 is objected to because of the following informalities: In line 3, “a stabilizing device acting in a longitudinal extension of the device” appears it should read as “a stabilizing device acting in a longitudinal extension of the handle”, since the stabilizing device is an extension of the handle and not the device. Appropriate correction is required.
2. Claim 20 is objected to because of the following informalities: It is unclear to the Examiner what the word “its” refers to in the claim. Appropriate correction is required.
3. Claim 21 is objected to because of the following informalities: Claim 21 fails to further limit Claim 18, since Claim 18 already discloses the device is comprised of foam. Appropriate correction is required.
4. Claim 47 is objected to because of the following informalities: “10 mm,” should read as “10 mm.”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 18-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. Claims 18 is drawn towards the embodiment shown in Figures 9A and 9B, while Claims 20 and 23-27 are drawn towards embodiments as shown in Figures 2, 4A, 4B, 6A, 6B, 7A, 7B, 8A and 8B. Dependent claims 20 and 23-27, in combination with Claim 18 constitutes a mixture of embodiments, not disclosed in the specification. Furthermore, Claims 22, 25, 29-33, 35-39, 41-45 and 48 all contain new matter; none of the claimed positive engagement element profiles are supported by the current specification, nor are the claimed ranges supported by the current specification.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 18-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 discloses “a device” in the preamble, while claiming “a device” in line 2 of the claim. It is unclear to the Examiner if the device claimed in line 2 is the same device as in the preamble, or if the two devices are different. Correction is required.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 18, 21 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Maksem et al (6,346,086 B1).

Maksem et al disclose a cervical sampling means and further disclose a handle having a device at a front end thereof for collection of cells and a stabilizing device acting in a longitudinal extension of the device, the device being embodied as a cap arrangement and fixed on a carrier, the carrier including a base surface with a diameter smaller than a diameter of the base surface of the device, the stabilizing device is embodied as a tip projecting into the device, the tip being surrounded on all sides by a foam material, wherein the device is embodied as a cone tapering towards the front and the handle has a predetermined breaking point; the device is composed of foam material; and the stabilizing device has a length of 90% of the length of the device. See Figure 5.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maksem et al (6,346,086 B1) as applied to claim 18 above, and further in view of Strickland et al (5,191,899).

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Maksem et al, as discussed above, disclose a cervical cell sampling means but fail to disclose the device is arranged to rotate relative to the handle.

Strickland et al disclose a cervical cell sampling means and further disclose the device is arranged to rotate relative to the handle. See Figure 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Maksem et al to include the ability of the device to rotate relative to the handle, as per the teachings of Strickland et al, since it would provide a means of removing the acquired cell samples for analysis.

13. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maksem et al (6,346,086 B1) as applied to claim 18 above, and further in view of Bayne (4,754,764).

Maksem et al, as discussed above, disclose a cervical cell sampling means but fail to disclose the handle is 200mm.

Bayne discloses a cervical cytology device and further discloses the handle is 200mm. See Column 3, lines 58-59

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Maksem et al to include a handle being 200mm long, as per the teachings of Bayne et al, since it would provide a handle that is long enough to grip when the sampling means is fully inserted into the patient's vagina.

14. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maksem et al (6,346,086 B1) as applied to claim 18 above, and further in view of Hedberg et al (5,623,941).

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Maksem et al, as discussed above, disclose a cervical cell sampling means but fail to disclose the handle includes one of an angular cross-section and a round cross-section with a structured surface.

Hedberg et al disclose a cervical sampling device and further disclose the handle includes one of an angular cross-section and a round cross-section with a structured surface. See Figures 2 and 3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Maksem et al to include the use of a handle with an angular cross-section or a round cross-section with a structured surface, as per the teachings of Hedberg et al, since it would allow the operator to easily manipulate the sampling device while providing an adequate grip while wearing surgical gloves.

15. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maksem et al (6,346,086 B1) as applied to claim 18 above, and further in view of Jacobs et al (5,863,961).

Maksem et al, as discussed above, disclose a cervical cell sampling means comprised of foam but fail to disclose the foam has a compressive strength of 4 kPa.

Jacobs et al disclose flexible polyurethane foams and further disclose the foam has a compressive strength of 4 kPa. See Column 1, lines 28-34.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Maksem et al to include the compressive strength of the foam as being 4 kPa, as per the teachings of Jacobs et al, since it would

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provide a flexible foam tip for acquiring cell samples, while decreasing the likelihood of injury during the cell sampling procedure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmál whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmál/  
Examiner, Art Unit 3736